510(k) SUMMARY of Safety and Effectiveness

This following summary is provided as part of this Premarket Notification in compliance with and based on the format set forth in the Final Rule as published in the Federal Register, December 14, 1994. (See 21 CFR § 807.92)

(1) Submitters Name / Contact Person:

Viztek, Inc.
6491 Powers Ave.
Jacksonville, Florida 32217

Contact Person: Josip Cermin, President
Tel.: (904) 733-3656 X 25
Fax: (904) 733-8479
E-mail: jcermin@world-1.com

Date prepared: November 20, 2000

(2) Name of device:

Trade Name: Onyx-RAD Telemedicine PACS
Common Name: Medical image workstation system, PACS.
Classification Name: §892.2050 Picture archiving and communications system.

(3) Identification of predicate devices:

Manufacturer	Device	510(k) Number
Applicare Medical Imaging (General Electric)	Radworks System	K962699
Applicare Medical Imaging (General Electric)	Radworks w/QC Module	K982862

(4) Description of the device:

The Onyx-RAD Telemedicine PACS Medical Image Management system is a multi-modality comprehensive image presentation software system intended for acceptance, transfer, display, storage and digital processing of medical images.

Onyx-RAD offers full compliance with DICOM 3.0 file formats and JPEG Standards that permit transfer of image data with medical imaging equipment.

The Workstation features PC Computer based hardware and Microsoft Windows NT operating system and incorporates SMPTE Test Pattern files.

(5) A statement of the intended use of the device:

The Onyx-RAD Telemedicine PACS Medical Image Management system is intended for acceptance, transfer, display, storage and digital processing of medical images.

Its hardware components may include digitizers, workstations, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices and hardcopy devices.

The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(6) Predicate Device Comparison:

The Onyx-RAD Telemedicine PACS is substantially equivalent to similar features in the predicate device and has the same intended uses and technological characteristics. The different features included in the Onyx-RAD software do not affect the safety or effectiveness of the device.

The device complies with the following voluntary standards as "Special Controls" to ensure safe and effective use:

- ACR/NEMA Digital Imaging and Communications in Medicine (DICOM) standard
- Joint Photographic Experts Group (JPEG) standard
- Society of Motion Picture and Television Engineers (SMPTE) Test Pattern

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2001

Josip Cermin
President
Viztek, Inc.
6491 Powers Ave.
JACKSONVILLE FL 32217

Re: K003607
Onyx-Rad Telemedicine Pacs
Dated: November 20, 2000
Received: November 22, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Cermin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

2.0 FDA Indication for use form.

510(k) Number (if Known): K003607

Device Name: Onyx-RAD Telemedicine PACS

Indications For Use:

The Onyx-RAD Telemedicine PACS Medical Image Management system is intended for acceptance, transfer, display, storage and digital processing of medical images.

Its hardware components may include digitizers, workstations, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices and hardcopy devices.

The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003607